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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,368	11/03/1997	GARRY P. NOLAN	A-64260-2 DI	9991

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	30

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/963,368	NOLAN, GARRY P.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *22,26,27* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

Claims 16-31 are pending in the application.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 16-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a practical asserted utility or a well-established utility.

The claimed molecular library of retroviruses comprising at least 10^{1} different biased randomized nucleic acids lacks patentable utility. The claimed libraries are starting materials comprising of different components and are not isolated or purified product(s) but rather, products that are similar to those found in nature. The libraries, which are nothing more than a collection of individual products, are alleged in the

specification, as useful for screening for a final product, the proteins. It is this final product that is stated to possess a practical utility e.g., altering the phenotype of the cell. 35 USC 101 is clear in its requirement that a patent is granted for a **useful product** and not an impure, unisolated starting material from which the ultimate functional product can be obtained. All collection of existing materials or things, whether natural or non-natural, essentially undergoes a screening procedure to obtain an ultimate functional desired product.

Claims 16-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a practical asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See the rejection above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

In view of applicant's argument that claim 29 finds support in the specification at e.g., page 40, lines 28-31 which discusses screening "intracellular peptides" for agents that "block the expression or function of ..oncogenes…", the rejection of claim 29 is withdrawn.

Claims 15-31 are rejected under 35 U.S.C. 112, first paragraph, for lack of enabling disclosure for reasons advanced at paragraph 7, pages 3-5 of the last Office action, 4/11/02.

In view of applicant's argument the rejection of the claims under this statute is withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 16 and 21 are indefinite in the recitation of "encoding" since there are no method steps that recite for said encoding. The term is more appropriate for method rather than composition claim. A composition should characterize only the components present therein. Furthermore, the claim is confusing as to which compound is desired, nucleic acid or peptide. The metes and bounds of the retroviral constructs or what constitutes a construct, within the claimed invention, are indefinite.

B). The recited "plurality of randomized peptides" (claims 17-20) lacks antecedent support and is inconsistent with the base claim which does not recite for said plurality but only a randomized peptide.

C). Claims 22 is confusing and does not further limit claim 21 since it is assumed that the retroviral constructs is inherently integrated into the cells. "The cellular genome" lacks antecedent basis of support from the base claim.

D). Claims 23-25 do not further limit the base claim and broadens the base claim. The base claim does not recite encoding for a fusion partner. Rather, it encodes only randomized peptide. Furthermore, it is not clear, within the claimed context, what constitutes a fusion **partner**. How does the random nucleic acid become a partner of a fusion? Is the fusion within the constructs or outside the constructs? The metes and bounds of the fusion partner are therefore unclear and confusing as it covers different kinds, length and etc. of sequences, especially in the absence of positive showing in the specification.

E). Claims 29-31 are confusing in the recitation of "intracellularly expressing" as this language is a method step. Also, "is linked". See the rejection under D) above for claims 30 and 31.

F). Claim 29 is a duplicate of claim 21. It is considered that the cells in claim 29, is but the same cell of claim 21. Claim 21 would therefore similarly express said peptide intracellularly.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-50, 53 of copending Application No. 09/918,601('601 application) or claims 23-26 and 31-38 of S.N. 727,715('715 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed molecular library is an obvious variant of molecular library of the **e.g.**, '601 application, except the '601 application recites a library with stop codons of the same library. However, it is considered that the instant molecular library would obviously contain a stop codon such that the desired molecular library is achieved.

The fusion protein is similarly recited in each of the copending applications '715 and '368.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18, 21, 22, 23, 27, 29 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Jenkins (The EMBO Jrnl., 1995).

Jenkins discloses at page 4277, col. 1 and col. 2, a molecular library of retroviruses comprising a construct of random point mutants inserted en masse into a retroviral expression vector. The resultant retroviruses are then used to infect a murine factor-dependent haemotopoietic cell line. See further Figure 2 and page 4285. The library contains 10^4 viral

clones. See page 4283 as to the fusion protein containing dimerization. The library of Jenkins is biased in that only a portion of the polypeptide is randomized at certain positions while maintaining the rest of the polypeptide constant i.e., biased. Jenkins, which discloses specific molecular library of hbc, therefore fully meets the broad claimed molecular library of retroviruses containing randomized nucleic acids.

Claims 16-24, 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Whitehead et al (Mol. And Cell Biol., 2/1995).

Whitehead basically discloses, at page 704, Materials and Methods and page 709 col. 1, the same random library of retroviruses using oncongenes in mammalian fibroblasts cell. The library of Whitehead is biased in that only a portion of the polypeptide is randomized at certain positions while maintaining the rest of the polypeptide constant i.e., biased. Whitehead which discloses specific molecular library of oncogenes therefore fully meets the broad claimed molecular library of retroviruses containing randomized nucleic acids.

Claims 16-24, 29-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Pan et al (PNAS, 12/95).

Pan et al discloses a RNA library containing, 10^{15} different sequences, with a random sequence at a central 4-nt region, page 11509, col. 2 up to page 11510, col. 1. The library was incubated with retrovirus, RSV that forms the retroviral RNA complex. The complex was then mixed with quail fibrosarcoma cells (QT6 cell line, a cellular library of mammalian cells as claimed). The viral proteins from cell lysates, encoded by the RNA, are recovered. See further the RESULTS section at page 11510. The specific retrovirus constructs and mammalian cell containing the constructs of Pan fully meets the claimed molecular library of retroviruses.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Jenkins et al or Whitehead or Pan in view of Nilsson et al (Current Opinion in Structural biology, 1992).

Each of Jenkins, Whitehead and Pan is discussed, above. Each of these references does not teach a fusion partner. Nilsson discloses gene fusion techniques and the motivation derive in using said gene fusion techniques i.e., it facilitate purification of recombinant proteins from a crude extract and provides stability to a protein. See e.g., pages 569-573. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse the retroviral library of any one of Jenkins, Whitehead or Pan for the motivation provided by Nilsson, above i.e., stabilization of the protein and easy purification of the fused protein.

In view of the new rejections, supra, the rejections of the previous Office action are moot.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stemmer discloses a method for recombining n.a.

No claim is allowed.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
October 18, 2002